UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PROGRAF ANTITRUST LITIGATION	MDL No. 2242 Master File No. 1:11-md-2242-RWZ
THIS DOCUMENT RELATES TO: All Indirect Purchaser Actions	**Hon. Rya W. Zobel**

ANSWER OF DEFENDANT ASTELLAS PHARMA US, INC.
TO INDIRECT PURCHASER PLAINTIFFS'
CONSOLIDATED CLASS ACTION COMPLAINT

Defendant Astellas Pharma US, Inc. ("Astellas"), by its undersigned attorneys, hereby answers the Indirect Purchaser Plaintiffs' Consolidated Class Action Complaint (the "Complaint"). This Answer is based upon Astellas's investigation to date, and Astellas reserves the right to amend this Answer during the course of the litigation. Any allegation not expressly admitted is denied.[1] Astellas states as follows:

INTRODUCTORY PARAGRAPH

Astellas admits that Plaintiffs purport to identify the basis for facts and claims included in the Complaint. Astellas denies that Plaintiffs' allegations are correct or have a factual basis, denies that it has violated any law, and denies that this action may proceed as a class action.

NATURE OF ACTION

1. Astellas admits that its branded tacrolimus drug product Prograf® has immunosuppressive properties and is used to prevent organ rejection in patients who have received heart, kidney, or liver transplants. Astellas admits that Plaintiffs purport to bring the

[1] The Complaint contains headings that are not substantive allegations, and to which no answer is required; to the extent that those headings are substantive allegations to which an answer is required, Astellas denies the allegations.

action described in Paragraph 1, but Astellas denies that it has violated any law, denies that this action may proceed as a class action, and denies that Plaintiffs or the putative class are entitled to damages.

2. Astellas admits that Prograf is the brand name of its drug tacrolimus, and that Astellas Pharma US, Inc. sells Prograf. However, Astellas denies that Astellas Pharma US, Inc. manufactures Prograf; instead, affiliates of Astellas Pharma US, Inc. manufacture Prograf. Astellas admits that the U.S. Food and Drug Administration ("FDA") approved Prograf as an immunosuppressant in 1994 and that Astellas was the only source of FDA-approved tacrolimus in the United States from 1994 to 2009. However, Astellas denies that it was the sole source of tacrolimus outside the United States. Astellas admits that it filed a citizen petition (the "Citizen Petition") with the FDA on September 21, 2007 that requested, among other things, that the FDA require that bioequivalence studies for orally administered immunosuppressants used in the transplant population and characterized by a narrow therapeutic index be conducted in transplant patients as well as healthy subjects; Astellas denies that the requests in the Citizen Petition applied to generic tacrolimus products only. Astellas admits that U.S. Patent No. 4,894,366, which covered Prograf, expired on April 8, 2008, but Astellas denies that it filed the Citizen Petition as "generic competition for the drug was about to commence" because that allegation is vague and imprecise and so Astellas is unable to respond. Astellas admits that it filed a supplement to the Citizen Petition on September 11, 2008, but Astellas denies that the FDA "rejected" the Citizen Petition and Supplement: the FDA granted one of the Citizen Petition's requests. Astellas admits that it filed a motion for a temporary restraining order and preliminary injunction (the "TRO Motion") requesting that FDA revoke approval of generic tacrolimus products until the agency required bioequivalence studies in the patient population and revised

labeling requirements for such drugs, and that the U.S. District Court for the District of Columbia denied Astellas's motion in 2009.

3. Astellas admits that it was aware that manufacturers would likely seek FDA approval to sell generic versions of tacrolimus after the expiration of all patents covering Prograf to which Astellas had rights, but otherwise denies the allegations of Paragraph 3.

4. Astellas denies the allegations of Paragraph 4, except that it admits (1) it filed the Citizen Petition that the FDA denied in part, and (2) Astellas certified that the information and views on which the Citizen Petition relied included data and information known to Astellas to be unfavorable to the Citizen Petition.

5. Astellas admits that Plaintiffs purport to bring the action described in Paragraph 5, but otherwise denies the allegations of Paragraph 5. Astellas specifically denies that this action may proceed as a class action, that Astellas violated any law, and that Plaintiffs are entitled to damages.

6. Astellas admits that Plaintiffs purport to bring the claim described in Paragraph 6, but otherwise denies the allegations of Paragraph 6 and specifically denies that Astellas was unjustly enriched.

7. Astellas admits that Plaintiffs purport to bring this action as representatives of the putative class described in Paragraph 7, but denies that it engaged in any anticompetitive or wrongful conduct, denies that this matter may be certified as a class action, and denies any remaining allegations of Paragraph 7.

PARTIES

8. Astellas denies that it engaged in any illegal or wrongful conduct and that Plaintiff Plumbers and Pipefitters Local 572 Health and Welfare Fund was injured by any of

Astellas's conduct. The second and third sentences of Paragraph 8 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the statutes cited in Paragraph 8. Astellas lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 8 and therefore denies the same.

9. Astellas denies that it engaged in any illegal or wrongful conduct and that Plaintiff New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund was injured by any of Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 9 and therefore denies the same.

10. Astellas denies that it engaged in any illegal or wrongful conduct and that Plaintiff Louisiana Health Service Indemnity Company, d/b/a Bluecross/Blueshield of Louisiana was injured by any of Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 10 and therefore denies the same.

11. Astellas denies that it engaged in any illegal or wrongful conduct and that Plaintiff Judith Carrasquillo was injured by any of Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 11 and therefore denies the same.

12. Astellas denies that it engaged in any illegal or wrongful conduct and that Plaintiff Janet M. Paone ("Paone") was injured by any of Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 12 and therefore denies the same.

13. Astellas admits the allegations in Paragraph 13 except that it denies that it owns a facility in Massachusetts.

JURISDICTION AND VENUE

14. Astellas admits that Plaintiffs purport to bring the action described in Paragraph 14. Astellas lacks knowledge or information sufficient to form a belief about the residence of the Plaintiffs and therefore denies the same. The remaining allegations purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the remaining allegations of Paragraph 14.

15. Astellas admits that it transacts business within the District of Massachusetts and that it can be found in this district. The remaining allegations in Paragraph 15 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the remaining allegations of Paragraph 15.

REGULATORY BACKGROUND AND FDA TREATMENT OF GENERIC DRUGS

16. The allegations in Paragraph 16 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the Food, Drug and Cosmetics Act ("FDCA") and related federal regulations and case law.

17. Astellas admits that Congress adopted the Hatch-Waxman amendments to the FDCA in 1984. The remaining allegations in Paragraph 17 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. To the extent Paragraph 17 purports to represent or state the purpose, motive or reason for

legislative action, Astellas lacks knowledge or information sufficient to form a belief about the truth of those allegations and therefore denies them.

18. The second sentence of Paragraph 18 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to applicable state laws concerning prescriptions and generic substitution. Astellas lacks knowledge or information sufficient to form a belief about the allegations in the remaining portions of Paragraph 18, in part because they make generalized assertions regarding a broad range of circumstances, and in part because the terms "typically," "significantly," and "automatically" are subjective and vague, and on that basis Astellas denies those allegations.

19. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 19, in part because they make generalized assertions regarding a broad range of circumstances, and in part because the terms "predictably" and "substantially" are subjective and vague, and on that basis Astellas denies those allegations.

20. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 20, because they make generalized assertions regarding a broad range of circumstances, and on that basis Astellas denies those allegations.

21. Astellas admits that the footnote appended to Paragraph 21 purports to quote from, paraphrase, and characterize the text of the FDCA, but denies the allegations of that footnote to the extent that it mischaracterizes, inaccurately or selectively quotes, or adds emphasis to that document; Astellas refers the Court to the text of the statute. Astellas further states that Paragraph 21, including the footnote appended thereto, purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and

case law. To the extent Paragraph 21 purports to represent or state the purpose, motive or reason for legislative action, Astellas lacks knowledge or information sufficient to form a belief about the truth of those allegations and therefore denies them.

22. Astellas admits that from time to time the FDA may issue guidance related to the bioequivalence of drugs, either in draft or final form, but otherwise Paragraph 22 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. Astellas also lacks sufficient knowledge or information to form a belief as to the truth as to whether any particular guidance document "articulat[es] the [FDA's] current thinking on the issue," and so denies the allegation.

23. Astellas admits that the FDA may at times assign certain generic drugs an AB rating, but otherwise Paragraph 23 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law, as well as applicable federal and state laws concerning prescriptions and generic substitution.

24. Paragraph 24 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. To the extent Paragraph 24 purports to represent or state the purpose, motive or reason for legislative action, Astellas lacks knowledge or information sufficient to form a belief about the truth of those allegations and therefore denies them.

25. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 25, in part because the terms "substantially," "top-selling," and "nearly all" are subjective and vague, and on that basis Astellas denies those allegations.

26. Paragraph 26 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. To the extent Paragraph 26 purports to represent or state the purpose, motive or reason for legislative action, Astellas lacks knowledge or information sufficient to form a belief about the truth of those allegations and therefore denies them.

27. The third sentence of Paragraph 27 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent an answer is required, Astellas refers the Court to applicable state laws concerning prescriptions and generic substitution. Astellas lacks knowledge or information sufficient to form a belief about the allegations in the remaining portions of Paragraph 27, in part because they make generalized assertions regarding a broad range of circumstances, and in part because the terms "typically" and "much less" are subjective and vague, and on that basis Astellas denies those allegations.

28. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 28, in part because they make generalized assertions regarding a broad range of circumstances, and in part because the terms "typically" and "similarly" are subjective and vague, and on that basis Astellas denies those allegations.

29. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 29, in part because they make generalized assertions regarding a broad range of circumstances, and on that basis denies those allegations.

30. Astellas denies the allegations of the second sentence of Paragraph 30 to the extent they purport to relate to Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 30 insofar as they concern other brand name pharmaceutical manufacturers and on that basis denies those allegations. Astellas lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 30, in part because they make generalized assertions regarding a broad range of circumstances, and on that basis Astellas denies those allegations.

CITIZEN PETITIONS TO FDA

31. Astellas admits that persons and entities may file citizen petitions with the FDA pursuant to section 505(b) and (j) of the FDCA, but otherwise states that the first sentence of Paragraph 31 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA, the federal regulations governing citizen petitions, and related case law.

32. Astellas lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of Paragraph 32 because they purport to represent or state the purpose, motive or reason for legislative or regulatory action, and Astellas therefore denies the same. The allegations in the second sentence of Paragraph 32 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the federal regulations governing citizen petitions.

33. Astellas admits that a citizen petition may contain scientific and technical information in support of its requests. The allegations in Paragraph 33 otherwise purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the federal regulations governing citizen petitions.

34. The allegations in Paragraph 34 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the federal regulations governing citizen petitions.

35. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 35, in part because they make generalized assertions regarding a broad range of circumstances, and on this basis Astellas denies those allegations. Astellas specifically denies that the FDA has insufficient resources to consider and resolve citizen petitions or that it is incapable of summarily dismissing a frivolous citizen petition.

36. Astellas denies the allegations of Paragraph 36 to the extent they purport to relate to Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 36 as they pertain to other brand name pharmaceutical manufacturers and on that basis denies those allegations.

37. Astellas denies the allegations of Paragraph 37 to the extent they purport to relate to Astellas's conduct. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 37 insofar as they concern other brand name pharmaceutical manufacturers and on that basis denies those allegations.

38. Astellas admits that Paragraph 38 purports to quote from, paraphrase, and characterize a statement purportedly made by FDA Chief Counsel Sheldon Bradshaw, but denies the allegations of Paragraph 38 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that statement, and denies that the statement relates to Astellas in any way. Astellas denies any allegations that it has abused the citizen petition process, and denies any and all remaining allegations of Paragraph 38 that may relate to it. Astellas lacks knowledge

or information sufficient to form a belief about the allegations in Paragraph 38 insofar as they concern other filers of citizen petitions, and on that basis denies those allegations.

39. Astellas admits that Paragraph 39 purports to quote from, paraphrase, and characterize a statement purportedly made in 2006 by an employee of the FDA, but denies the allegations of Paragraph 39 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that statement, and denies that the statement relates to Astellas in any way. Astellas lacks knowledge or information sufficient to form a belief about any remaining allegations in Paragraph 39, and on that basis denies the same.

40. Astellas admits that the second sentence of Paragraph 40 purports to quote from, paraphrase, and characterize a statement purportedly made in 2006 by an employee of the FDA, but denies those allegations to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that statement, and denies that the statement relates to Astellas in any way. Astellas lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 40 and therefore denies them.

41. Astellas admits that that it filed a Citizen Petition with the FDA on September 21, 2007, six days before the 2007 amendments to the FDCA took effect. Paragraph 41 otherwise purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. Further, to the extent Paragraph 41 purports to represent or state the purpose, motive or reason for legislative action, Astellas lacks knowledge sufficient to form a belief about the truth of those allegations and therefore denies them. Astellas denies any remaining allegations in Paragraph 41.

FACTUAL BACKGROUND

A. Organ Transplantation, Immunosuppressant Therapy, and Prograf

42. Astellas admits the allegations in Paragraph 42 except that Astellas states that allografts may be obtained from persons who are either related or unrelated to the transplant recipient.

43. Astellas admits that allografts account for many human transplants and that heart, lungs, heart/lung, kidney, pancreas, and liver are among the most common solid organ allograft transplants. Astellas further admits that donor organs for allograft transplants may be obtained from deceased, living related, or living unrelated donors.

44. Astellas admits that the Organ Procurement and Transplantation Network website indicates that there currently are more than 100,000 patients awaiting organ transplant, http://optn.transplant.hrsa.gov/, and that 27,824 organ transplants were conducted in 2009, http://www.srtr.org/annual_reports/2010/107_dh.htm. Astellas further admits that there is a severe scarcity of organs available for patients in need of organ transplants and that, as a consequence, efforts should be made to prevent organ rejection, including monitoring patients for organ rejection and treating patients as necessary. As to the second footnote appended to Paragraph 44, Astellas admits that organ rejection occurs when the body's immune system recognizes the organ as foreign and attacks it, but Astellas denies that such rejection necessarily leads to transplant failure and removal of the organ from the body.

45. Astellas admits that physicians take steps before and after transplant procedures to try to reduce the risk of organ rejection in their patients. Astellas further admits that the chance of rejection can be reduced by serotype testing before surgery and through the use of immunosuppressant drugs after surgery.

46. Astellas admits that there are multiple classes of immunosuppressants, and that calcineurin inhibitors are one such class. Astellas admits that tacrolimus (including Prograf) and cyclosporine are calcineurin inhibitors, but denies that sirolimus (rapamycin) is a calcineurin inhibitor. Astellas denies that calcineurin inhibitors "prevent the immune system cascade that leads to organ rejection." Astellas admits the remaining allegations of Paragraph 46.

47. Astellas admits that, in many cases, immunosuppressants are administered in combination with antifungal, antibacterial, antiviral or other agents used to support the patient's weakened immune state or manage other diseases.

48. Astellas admits the allegations in Paragraph 48 except that Astellas states that blood level monitoring does not "avoid" adverse events, but rather minimizes the chance of adverse events.

49. Astellas admits the allegations in Paragraph 49 except that Astellas states that (1) the FDA has not adopted a definitive list of NTI drugs, and (2) sub-therapeutic blood levels of tacrolimus or cyclosporine may result in rejection of the graft, loss of the transplanted organ or, in some cases, patient death.

50. Astellas admits that Prograf, the sole active ingredient of which is tacrolimus, is an immunosuppressant approved by the FDA to help prevent organ rejection following heart, kidney, or liver transplants. Astellas also admits that Astellas Pharma US, Inc. sells and markets Prograf, but denies that Astellas Pharma US, Inc. manufactures Prograf; instead, affiliates of Astellas Pharma US, Inc. manufacture Prograf. Astellas further admits that Prograf is produced by the bacteria *Streptomyces tsukubaensis*, but it denies that Prograf is "derived from a metabolite" produced by that bacteria.

51. Astellas admits the allegations of Paragraph 51.

52. Astellas admits that Prograf's label recommends that the capsule form of the drug product be taken orally twice daily and that Prograf can also be administered intravenously. Astellas lacks sufficient information to form a belief as to whether Prograf capsules are always administered orally twice daily. Astellas admits that Prograf's label includes the following black box warning: "Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe Prograf. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient." Astellas admits that another part of the Prograf label states: "Patients receiving Prograf injection should be under continuous observation for at least the first 30 minutes following the start of the infusion and at frequent intervals thereafter. If signs or symptoms of anaphylaxis occur, the infusion should be stopped. An aqueous solution of epinephrine should be available at the bedside as well as a source of oxygen."

53. Astellas admits that Prograf's label recommends that, for some types of transplants, doses of Prograf be decreased beginning four months post-transplant, relative to the amounts received immediately after transplantation. Astellas lacks sufficient information to form a belief as to whether dosages of tacrolimus always are decreased four to six months post-transplant, and on that basis denies the same.

54. Astellas admits the allegations in Paragraph 54.

55. Astellas denies the allegations in the first sentence of Paragraph 55. Astellas admits that it has marketed and sold Prograf in the U.S. However, Astellas lacks sufficient information to admit or deny the allegation that IMS Health reported to Plaintiffs that Astellas's

annual sales of Prograf were approximately $929 million in the twelve months ending 2009, and therefore denies the same.

B. Generic Versions Of Tacrolimus Prepare To Come To Market

56. Astellas admits that it was aware that manufacturers would likely seek FDA approval to sell generic versions of tacrolimus after the expiration of all patents covering Prograf to which Astellas had rights. Astellas admits (1) U.S. Patent No. 4,894,366, which covered Prograf, expired on April 8, 2008; (2) on December 28, 2006, Sandoz Inc. filed an ANDA to market and sell tacrolimus capsules in 0.5 mg, 1 mg, and 5 mg doses; (3) Watson, Dr. Reddy's, and Mylan also filed ANDAs to market and sell a generic tacrolimus product. Astellas denies any remaining allegations in Paragraph 56.

57. Astellas admits that companies seeking to market a generic tacrolimus product were required to gain FDA approval of an ANDA for that product before entering the market. Astellas lacks sufficient information to admit or deny the allegation that "[e]stablishing bioequivalence to the branded reference drug is key to ANDA approval," because that allegation is vague and imprecise, and on that basis Astellas denies the same. The allegations in the third, fourth, and fifth sentences of Paragraph 57 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law. Astellas admits that FDA has published bioequivalence guidance documents setting forth recommendations for conducting bioequivalence tests in particular situations, but Astellas lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the last sentence of Paragraph 57 because that sentence does not specify the guidance document at issue; on that basis, Astellas denies the allegations in the last sentence of Paragraph 57.

58. Paragraph 58 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to the text of the FDCA and related federal regulations and case law.

59. Astellas admits that in October 2000 the FDA published *Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations* ("General Bioequivalence Guidance") and that the FDA published a revision of this guidance document in March 2003. Astellas also admits that the remaining allegations of Paragraph 59 purport to characterize the General Bioequivalence Guidance, but Astellas denies the allegations in Paragraph 59 to the extent that they mischaracterize that document; Astellas refers the Court to the text of the General Bioequivalence Guidance.

60. Astellas denies any allegation that single-dose studies in healthy subjects were sufficient to test bioequivalence of different formulations of tacrolimus. Astellas lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' characterizations of the FDA's views and therefore denies those allegations. Astellas also lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences, in part because the allegations that single-dose studies "typically" are more sensitive than multiple-dose studies and that using transplant patients in bioequivalence studies "might confound or impede the analysis" are vague and overbroad; on these bases Astellas denies the allegations in the third and fourth sentences of Paragraph 60. Astellas denies any remaining allegations in Paragraph 60.

61. Astellas lacks sufficient information to admit or deny the allegations in the first sentence of Paragraph 61, because that allegation fails to identify the document or context in which the alleged recommendation was made. To the extent that the first sentence of Paragraph

61 refers to the General Bioequivalence Guidance, Astellas denies the allegations in that sentence on the ground that it is incomplete, because it does not acknowledge that, in the General Bioequivalence Guidance, the FDA importantly (1) recognized that "[i]n some instances," it may be appropriate to conduct bioequivalence studies in patients who suffer with the condition the drug is intended to treat, and (2) recommended that applicants "consider additional testing and/or controls" when submitting an ANDA for "narrow therapeutic index" drugs. Astellas admits that generic versions of cyclosporine have been approved based on single-dose bioequivalence tests in healthy subjects, but Astellas denies the allegations in the second sentence of Paragraph 61 as to immunosuppressant drugs other than cyclosporine because the identity of those drugs is not specified.

62. Astellas admits that, in May 2007, the FDA published in the Federal Register a notice of availability of a draft document entitled *Guidance for Industry, Bioequivalence Recommendations for Specific Products*, as well as of individual draft bioequivalence guidance documents for approximately 200 products, and solicited public comment on all of those documents. Astellas admits that tacrolimus was among the approximately 200 products listed in that Federal Register notice and for which a draft bioequivalence guidance document was prepared.

63. Astellas admits that Paragraph 63 purports to characterize and paraphrase the Draft Tacrolimus Guidance as to which the FDA sought public comments, but denies these allegations to the extent that they mischaracterize that document; Astellas refers the Court to the text of the Draft Tacrolimus Guidance. To the extent Paragraph 63 purports to represent or state the purpose, motive or reason for the recommendations in the Draft Tacrolimus Guidance, Astellas lacks knowledge or information sufficient to form a belief about the truth of those

allegations and therefore denies them. Astellas denies any remaining allegations in Paragraph 63.

64. Astellas admits that Paragraph 64 purports to characterize and paraphrase the Draft Tacrolimus Guidance as to which the FDA sought public comments, but denies these allegations to the extent that they mischaracterize that document; Astellas refers the Court to the text of the Draft Tacrolimus Guidance.

C. Astellas Files A Sham Petition Trying To Block Generic Tacrolimus

65. Astellas admits that it filed a Citizen Petition with the FDA on September 21, 2007, six days before the 2007 amendments to the FDCA took effect. Astellas also admits that Sandoz's ANDA to sell tacrolimus capsules, which had been filed on December 28, 2006 and was approved on August 10, 2009, was pending on September 21, 2007. Astellas denies the remaining allegations of Paragraph 65.

66. Astellas admits that in the Citizen Petition it asserted that single-dose bioequivalence studies in healthy subjects were insufficient to establish bioequivalence of different formulations of NTI immunosuppressant drugs and requested that FDA also require bioequivalence studies in transplant patients for such drugs. Astellas denies the remaining allegations of Paragraph 66, in part because the Citizen Petition did not concern an ANDA filed by Sandoz or any other applicant to market a generic tacrolimus product.

67. Astellas admits that Paragraph 67 purports to quote from the certification statement in its Citizen Petition, but Astellas denies the allegations of Paragraph 67 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that statement; Astellas refers the Court to the text of the Citizen Petition.

68. Astellas denies the allegations in Paragraph 68 except that it admits that it used single-dose studies in healthy subjects to establish the dose proportionality of different strengths of an immediate-release, twice-daily tacrolimus capsule formulation, Prograf.

69. Astellas admits that Paragraph 69 accurately quotes from a portion of a former version of Prograf's label (with the exception of the omission of "0" before ".5"), but denies the allegations in Paragraph 69 to the extent that they mischaracterize, selectively quote, or add emphasis to the label. Astellas admits that it did not discuss this portion of the Prograf label in its Citizen Petition, but Astellas denies that the quoted text was unfavorable to the requests made in the Citizen Petition.

70. Astellas admits that it used single-dose studies in healthy subjects to establish the dose proportionality of different strengths of an immediate-release, twice-daily tacrolimus capsule formulation, Prograf, for the purposes of gaining approval to market Prograf in other countries. Astellas admits that it did not discuss this information in its Citizen Petition, but denies that it was unfavorable to the requests made in the Citizen Petition. Astellas denies the allegation that it "made statements in submissions to foreign pharmaceutical regulatory agencies showing Astellas' reliance" on the single-dose studies described in Paragraph 70 because that allegation is vague and imprecise and so Astellas is unable to respond.

71. Astellas admits that (1) it filed an FDA Form 356h Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, which includes a certification that the submission was true and accurate, (2) as indicated on Prograf's label, Astellas used single-dose studies in healthy subjects to establish the dose proportionality of different strengths of an immediate-release, twice-daily tacrolimus capsule formulation, Prograf, and (3) it did not discuss this information in its Citizen Petition, although Astellas denies that this information was

unfavorable to the requests made in the Citizen Petition. Astellas denies the remaining allegations of Paragraph 71.

72. Astellas denies the allegations of Paragraph 72, including the allegation that the Citizen Petition failed to present evidence showing the insufficiency of single-dose studies in healthy subjects to establish bioequivalence of different formulations of NTI immunosuppressant drugs.

73. Astellas admits that the Citizen Petition set forth scientific studies challenging the FDA's position that single-dose bioequivalence studies in healthy subjects were adequate for NTI immunosuppressant drugs, but Astellas denies the allegations in the first sentence of Paragraph 73 to the extent they both mischaracterize the Citizen Petition and are vague and imprecise, and thus Astellas refers the Court to the text of that document. Astellas denies the remaining allegations of Paragraph 73.

74. Astellas admits that Paragraph 74 purports to paraphrase and characterize the Citizen Petition, but Astellas denies the allegations of Paragraph 74 to the extent that they mischaracterize that document; Astellas refers the Court to the text of the Citizen Petition. Astellas admits that the FDA approved generic formulations of cyclosporine, another immunosuppressant drug product, on the basis of single-dose bioequivalence studies in healthy subjects. Astellas denies any remaining allegations in Paragraph 74.

75. Astellas admits that its Citizen Petition relied in part on the 2006 Qazi study and the 2005 Taber study. Astellas further admits that the Taber study showed that the incidence of biopsy-proven acute rejection ("BPAR") was significantly higher among 100 patients who received kidney transplants between January 1999 and May 2001 and who were treated with branded cyclosporine than among 88 patients who received kidney transplants between May

2001 and July 2002 and were treated with generic cyclosporine. Astellas admits that its Citizen Petition described the result of the Taber study as "clinically significant" because BPAR is correlated with an increase in graft loss and patient mortality. Astellas denies all remaining allegations in Paragraph 75, and specifically denies that it "failed to disclose" any limitations in or of the Taber study or the Qazi study, and that it drew "bold scientific conclusions that were unsupported in light of the inherent limitations of the [Qazi] study."

76. Astellas admits that the first three sentences of Paragraph 76 purport to paraphrase and characterize the content of the Citizen Petition, but Astellas denies the allegations of Paragraph 76 to the extent they mischaracterize the Citizen Petition; Astellas refers the Court to the text of the Citizen Petition. Astellas admits that the final sentence of Paragraph 76 accurately quotes from a portion of the FDA's Response to the Citizen Petition (with some modifications), but Astellas denies those allegations to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to the FDA's Response; Astellas refers the Court to the text of that document. Astellas denies the remaining allegations in Paragraph 76.

77. Astellas denies the allegations in Paragraph 77.

78. Astellas admits that in the Citizen Petition it stated that (1) "when both tacrolimus formulations," Prograf and the extended release version, Advagraf, "were studied in de novo kidney and liver transplant patients, exposure to tacrolimus was significantly reduced on day 1 in patients treated with extended-release tacrolimus," (2) "despite meeting the applicable bioequivalence standard in healthy volunteers as well as stable kidney and liver transplant recipients, the findings" of pharmacokinetic studies "did not successfully predict the pharmacokinetics in de novo kidney or liver transplant patents during the immediate post-transplant period," (3) "the finding illustrates that there can be differences between the

bioequivalence results for different formulations of tacrolimus in healthy volunteers as compared to transplant patients early after surgery," and (4) "[g]iven the potential deleterious effect in transplant patients and the consequences of losing a transplanted organ, FDA bioequivalence standards should require the evaluation of pharmacokinetics in transplant patents in the immediate post-transplant period." Astellas otherwise denies the allegations of Paragraph 78 on the ground that they mischaracterize the Citizen Petition; Astellas refers the Court to the text of the Citizen Petition.

79. Astellas admits that Paragraph 79 purports to quote from and characterize the FDA's Response to the Citizen Petition, but Astellas denies the allegations of Paragraph 79 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to the FDA's response; Astellas refers the Court to the text of that Response. Astellas denies the remaining allegations of Paragraph 79 and specifically denies that "[t]he Advagraf argument was entirely irrelevant."

80. Astellas admits that Paragraph 80 purports to paraphrase and characterize Astellas's Citizen Petition and its Memorandum of Points and Authorities in Support of its TRO Motion ("TRO Memorandum"), but Astellas denies the allegations of Paragraph 80 to the extent that they mischaracterize those documents; Astellas refers the Court to the text of the Citizen Petition and the text of the TRO Memorandum. Astellas denies the remaining allegations of Paragraph 80.

81. Astellas admits that, on August 10, 2009, the FDA issued a fifteen-page decision on its Citizen Petition, which it had submitted on September 21, 2007, that granted one of the requests Astellas made in the Citizen Petition and denied the others. Astellas denies the allegation that the FDA's decision "did not change or alter any of its actions" because that

allegation is vague and imprecise and so Astellas is unable to respond. Astellas admits that the FDA approved on August 10, 2009 Sandoz's ANDA for generic tacrolimus (which had been filed on December 28, 2006), and that Sandoz's generic tacrolimus formulation came to market the next day. Astellas denies the allegations in the last sentence of Paragraph 81 because it fails to state which other Generic was approved on which date. Astellas denies the remaining allegations in Paragraph 81, including the allegation that the FDA "recognized" the Citizen Petition as a "sham."

82. Astellas admits that Paragraph 82 purports to quote from, characterize, and paraphrase the FDA's Response to the Citizen Petition. While Astellas admits that the second sentence of Paragraph 82 accurately quotes from a portion of the FDA's Response to the Citizen Petition (with the exception of the omission of the word "not" before "be detected"), Astellas denies the allegations of Paragraph 82 to the extent that they mischaracterize, selectively quote, or add emphasis to the FDA's Response; Astellas refers the Court to the text of that document. Astellas denies the remaining allegations of Paragraph 82.

83. Astellas denies the allegations of Paragraph 83.

84. Astellas admits that Paragraph 84 purports to quote from, paraphrase, and characterize the FDA's Response to the Citizen Petition, but Astellas denies the allegations of Paragraph 84 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to the FDA's Response; Astellas refers the Court to the text of that document. Astellas denies that the requests made in the Citizen Petition that are referenced in Paragraph 84 were "minor" in nature. Astellas denies the remaining allegations in Paragraph 84.

85. Astellas admits that Paragraph 85 purports to paraphrase and characterize the FDA's Response to the Citizen Petition, but Astellas denies the allegations of Paragraph 85 to

the extent that they mischaracterize or add emphasis to the FDA's Response; Astellas refers the Court to the text of that document. Astellas denies the remaining allegations in Paragraph 85.

86. Astellas admits that the first sentence of Paragraph 86 purports to quote from, paraphrase, and characterize the FDA's Response to the Citizen Petition, but Astellas denies those allegations to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to the FDA's Response; Astellas refers the Court to the text of that document. Astellas lacks sufficient information to admit or deny that the FDA has "*always* required" differentiation among dosages and that "this was already FDA policy," and therefore denies those allegations. Astellas denies the remaining allegations in Paragraph 86.

D. After The FDA Rejects Its Sham Petition, Astellas Unsuccessfully Attempts To Enjoin The Agency From Approving Generic Tacrolimus

87. Astellas admits that on August 11, 2009, the day after the FDA denied the Citizen Petition and approved Sandoz's ANDA and the same day that Sandoz's generic tacrolimus capsules came to market, Astellas filed a motion for a TRO in the District Court for the District of Columbia that sought to revoke FDA approval of generic formulations of tacrolimus until the FDA adopted the requests made in the Citizen Petition. Astellas denies the remaining allegations of Paragraph 87.

88. Astellas admits that its Memorandum of Points and Authorities in Support of its TRO Motion ("TRO Memorandum") argued that the FDA acted arbitrarily and capriciously in denying all but one of the Citizen Petition's requests. Astellas also admits that Paragraph 88 purports to paraphrase and characterize Astellas's TRO Memorandum, but Astellas denies the allegations of Paragraph 88 to the extent that they mischaracterize that document; Astellas refers the Court to the text of the TRO Memorandum. Astellas denies any remaining allegations in Paragraph 88.

89. Astellas admits that Paragraph 89 purports to paraphrase and characterize Astellas's TRO Memorandum, but Astellas denies the allegations of Paragraph 89 to the extent that they mischaracterize that document; Astellas refers the Court to the text of the TRO Memorandum.

90. Astellas admits that Paragraph 90 purports to paraphrase and characterize Astellas's TRO Memorandum, but Astellas denies the allegations of Paragraph 90 to the extent that they mischaracterize that document; Astellas refers the Court to the text of the TRO Memorandum.

91. Astellas admits that the FDA opposed the TRO motion. Astellas also admits that Paragraph 91 purports to paraphrase and characterize the FDA's brief in opposition to Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 91 to the extent that they mischaracterize that document; Astellas refers the Court to the text of that brief.

92. Astellas admits that Paragraph 92 purports to quote from, paraphrase, and characterize the FDA's brief in opposition to the TRO Motion, but Astellas denies the allegations of Paragraph 92 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that legal brief. Astellas denies that its Citizen Petition delayed the approval of Sandoz's generic tacrolimus product and that Astellas attempted to block generic competition, and denies any remaining allegations of Paragraph 92.

93. Astellas admits that Paragraph 93 purports to paraphrase and characterize the FDA's brief in opposition to Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 93 to the extent that they mischaracterize that document; Astellas refers the Court to the text of that brief.

94. Astellas admits that Paragraph 94 purports to paraphrase and characterize the FDA's brief in opposition to the TRO Motion, but Astellas denies the allegations of Paragraph 94 to the extent that they mischaracterize that document; Astellas refers the Court to the text of that brief.

95. Astellas admits that Paragraph 95 purports to paraphrase and characterize the FDA's brief in opposition to the TRO Motion, but Astellas denies the allegations of Paragraph 95 to the extent that they mischaracterize that document; Astellas refers the Court to the text of that brief.

96. Astellas admits that on August 12, 2009, the same day that the FDA filed its brief in opposition to the TRO Motion, the district court denied Astellas's request for a TRO. Astellas also admits that the second sentence of Paragraph 96 purports to quote from, paraphrase, and characterize the district court's opinion denying Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 96 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that document; Astellas refers the Court to the text of that document.

97. Astellas admits that Paragraph 97 purports to quote from, paraphrase, and characterize the district court's opinion denying Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 97 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that document. Astellas further denies any remaining allegations in Paragraph 97.

98. Astellas admits that Paragraph 98 purports to quote from, paraphrase, and characterize the district court's opinion denying the TRO Motion, but Astellas denies the allegations of Paragraph 98 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that document. Astellas denies that the district court "recognized" or

concluded that the Citizen Petition was objectively baseless, and denies any remaining allegations in Paragraph 98.

99. Astellas admits that Paragraph 99 purports to paraphrase and characterize the district court's opinion denying Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 99 to the extent that they mischaracterize or add emphasis to that document.

100. Astellas admits that Paragraph 100 purports to quote from, paraphrase, and characterize the district court's opinion denying Astellas's TRO Motion, but Astellas denies the allegations of Paragraph 100 to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that document. Astellas denies any remaining allegations in Paragraph 100.

101. Astellas admits the allegations in Paragraph 101.

E. Astellas' Effort to Delay Generic Competition Is Anticompetitive Conduct Impacting Interstate Commerce

102. Astellas denies the allegations of Paragraph 102.

103. Astellas denies the allegations of Paragraph 103.

104. Astellas denies the allegations of Paragraph 104.

105. Astellas denies the allegations of Paragraph 105, including the allegation that the cyclosporine studies cited in the Citizen Petition did not support its position.

106. Astellas denies that its arguments concerning interpatient and intrapatient variability were "groundless." To the extent that the allegations in the first and second sentences of Paragraph 106 purport to state legal conclusions, an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies those allegations. Astellas further answers that it lacks knowledge or information sufficient to form a belief about the truth of the allegations regarding (1) what "the generic product relies on" and (2) statements that FDA

allegedly made in various documents, because the Complaint does not identify those documents or "these statements"; Astellas therefore denies the same. Astellas denies the remaining allegations in Paragraph 106.

107. Astellas denies the allegations of Paragraph 107.

108. Astellas denies the allegations in the first sentence of Paragraph 108. The second sentence of Paragraph 108 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the allegations in the second sentence of Paragraph 108. Astellas denies the allegations in the third sentence of Paragraph 108 in part because the phrases "these particular types of immunosuppressive drugs" and "routinely" are vague and imprecise, and because there is no basis for the allegation that doctors "would" detect "any problems." Astellas denies the allegations in the last sentence of Paragraph 108 because it does not identify the drug product to which it refers.

109. Astellas denies the allegations of Paragraph 109. Astellas further states that the FDA granted the Citizen Petition's request that generic manufacturers of immunosuppressant drugs be required to differentiate between dosage strengths by appropriate means.

110. Astellas admits that the third sentence purports to characterize and paraphrase the FDA's brief in opposition to the TRO Motion, but Astellas denies the allegations in that sentence to the extent that they mischaracterize that brief; Astellas refers the Court to the FDA's brief. Astellas admits that the Citizen Petition indicated that it was filed in response to the Draft Tacrolimus Guidance. Astellas denies the remaining allegations in Paragraph 110.

111. The allegations in the first sentence of Paragraph 111 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the allegations in the in the first sentence of Paragraph 111. Astellas

admits that Astellas Pharma US, Inc. marketed and sold Prograf during the purported class period, but Astellas denies that Astellas Pharma US, Inc. manufactured or distributed Prograf at that time; instead, affiliates of Astellas Pharma US, Inc. manufactured and distributed Prograf. Astellas admits that its activities were conducted throughout the United States. Astellas denies the remaining allegations in Paragraph 111.

112. Astellas admits that during the purported class period, in connection with the sale of Prograf, various forms of business communication and transactions were conducted by it throughout the United States. Astellas denies the remaining allegations in Paragraph 112.

113. Astellas denies the allegations in Paragraph 113.

F. Defendant's Conduct Is Not Immune Under The Noerr-Pennington Doctrine

114. Astellas denies the allegations of Paragraph 114.

115. Astellas denies the allegations of Paragraph 115. Astellas admits that the footnote appended to Paragraph 115 accurately quotes a portion of the FDA's Response to the Citizen Petition, but Astellas denies the allegation in that footnote to the extent that it mischaracterizes, selectively quotes, or adds emphasis to the FDA's Response; Astellas refers the Court to that document. Astellas lacks information to form a belief as to the truth of the allegation that the "FDA is not aware of [certain] safety signals" regarding generic cyclosporine drug products, and so denies that allegation, although Astellas asserts that a generic cyclosporine drug product was removed from the market due to safety concerns.

116. Astellas denies the allegations of Paragraph 116.

117. Astellas denies the allegations in Paragraph 117, except Astellas admits that the indented text in Paragraph 117 purports to quote from the complaint that Astellas filed against the FDA; but Astellas denies those allegations to the extent that they mischaracterize, inaccurately or selectively quote, or add emphasis to that complaint.

118. Astellas denies the allegations of Paragraph 118, except that it admits that, at some point before filing the Citizen Petition, it used single-dose studies in healthy subjects to establish the dose proportionality of different strengths of an immediate-release, twice-daily tacrolimus capsule formulation, Prograf, for purposes of gaining approval to market Prograf.

G. Astellas' Illegal Actions Harmed Indirect Purchaser Plaintiffs And The Class

119. Astellas denies the allegations in Paragraph 119.

120. Astellas denies the allegations in Paragraph 120.

121. Astellas denies the allegations in Paragraph 121.

122. The third sentence of Paragraph 122 purports to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas refers the Court to applicable state laws and regulations concerning pharmacy practice and "generic substitution." Astellas lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the practices of "many" third-party payors in undefined contexts referred to in the second to last sentence of Paragraph 122 and, on that basis, denies those allegations. Astellas denies all remaining allegations in Paragraph 122, in part because they make generalized assertions regarding a broad range of circumstances.

123. Astellas lacks knowledge or information sufficient to form a belief as to the allegations in the first sentence of Paragraph 123, in part because of the undefined context and the use of the vague terms "generally," "significant," "substantial," and unidentified "discounts," and on that basis denies those allegations. Astellas lacks knowledge or information sufficient to form a belief as to the allegations in the second sentence of Paragraph 123, and on that basis denies those allegations. Astellas admits that the last sentence of Paragraph 123 purports to paraphrase and characterize Astellas's TRO Motion, but Astellas denies those allegations to the

extent that they mischaracterize or add emphasis to that document; Astellas refers the Court to the TRO Motion. Astellas denies any remaining allegations in Paragraph 123.

124. Astellas denies the allegations in Paragraph 124.

H. The Relevant Market and Market Effects

125. Astellas denies the allegations in Paragraph 125.

126. Paragraph 126 purports to state a legal conclusion about the relevant product market to which no response is appropriate or required; to the extent that a response is required, Astellas denies the allegations of Paragraph 126.

127. To the extent Paragraph 127 purports to state a legal conclusion about relevant product markets, no response is required or appropriate; to the extent that a response is required, Astellas denies those allegations. Astellas denies the remaining allegations of Paragraph 127.

128. Astellas admits the allegations in the first sentence of Paragraph 128 and as to the second and third sentences, admits that tacrolimus has some advantages over cyclosporine and other immunosuppressants but states that those products have substantial sales. Astellas admits that doctors sometimes choose to prescribe tacrolimus over other competitive products for medical reasons even when tacrolimus is more expensive. Astellas denies that this shows that doctors are not sensitive to price differences between tacrolimus and other competitive products, and also denies that doctors are not price sensitive. Astellas denies all remaining allegations of Paragraph 128.

129. Astellas denies the allegations of Paragraph 129.

130. Astellas denies the allegations in Paragraph 130.

131. Paragraph 131 purports to state a legal conclusion about relevant geographic markets to which no response is required or appropriate; to the extent that a response is required, Astellas denies the allegations of Paragraph 131.

132. Astellas denies the allegations in Paragraph 132.

133. Astellas denies the allegations in Paragraph 133.

134. Astellas lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the unspecified "permissive and mandatory substitution laws and regulations" and the practices of third-party payors in undefined contexts referred to in the last sentence of Paragraph 134 and, on that basis, denies those allegations. Astellas denies the remaining allegations in Paragraph 134.

135. Astellas lacks knowledge or information sufficient to form a belief as to the allegations in the first sentence of paragraph 135, in part because of the undefined context and the use of the vague terms "generally," "significant," and unidentified "discounts," and on that basis denies those allegations. Astellas admits that the second sentence of Paragraph 135 purports to paraphrase and characterize the TRO Motion and affidavits Astellas filed in support thereof, but Astellas denies those allegations to the extent that they mischaracterize or add emphasis to those documents; Astellas refers the Court to the documents themselves. Astellas denies any remaining allegations to Paragraph 135, including the allegation that it engaged in "litigation to block entry of a generic version of Prograf."

136. Astellas denies the allegations in Paragraph 136.

CLASS ACTION ALLEGATIONS

137. Astellas admits that Indirect Purchaser Plaintiffs purport to seek for themselves and for the members of a putative class money damages and equitable remedies. Astellas denies that it engaged in anticompetitive conduct, denies that Indirect Purchaser Plaintiffs or any member of the putative class are entitled to any relief, denies that this action should be certified as a class action, and denies any remaining allegations of Paragraph 137.

138. Astellas admits that Indirect Purchaser Plaintiffs purport to bring this action as representatives of the putative class described in Paragraph 138, but denies that it engaged in any anticompetitive or unlawful conduct, denies that this matter may be certified as a class action, and denies any remaining allegations of Paragraph 138.

139. Astellas admits that Indirect Purchaser Plaintiffs purport to bring this action as representatives of a putative class that excludes the persons or entities described in subparagraphs (a) through (f) of Paragraph 139.

140. Astellas lacks knowledge or information sufficient to form a belief as to the truth of whether Indirect Purchaser Plaintiffs believe that the putative class members number in the tens-of-thousands. Astellas denies the remaining allegations in Paragraph 140.

141. Astellas lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 141 and on that basis Astellas denies those allegations.

142. Astellas lacks information sufficient to form a belief as to the allegations in the first sentence of Paragraph 142 and so denies those allegations. Astellas denies the remaining allegations in Paragraph 142.

143. Astellas has not yet undertaken discovery related to the allegations in Paragraph 143 and therefore lacks knowledge or information sufficient to form a belief as to the truth of such allegations and, on that basis, denies them.

144. Astellas lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 144 and, on that basis, denies those allegations.

145. Astellas denies the allegations in Paragraph 145.

146. Astellas denies the allegations in Paragraph 146.

147. Astellas denies the allegations in Paragraph 147.

148. Astellas lacks knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 148 regarding Plaintiffs' knowledge and, on that basis, denies the allegations in Paragraph 148.

COUNT I:
(Monopolization and Unfair and/or Deceptive Trade Practices Under State Law)

149. Astellas repeats, and incorporates by reference, the answers in ¶¶ 1 – 148 above.

150. Astellas admits that Plaintiffs purport to bring this action under the laws of the Indirect Purchaser States described in Paragraph 5 as representatives of the putative class described in Paragraph 7.

151. Astellas denies the allegations of Paragraph 151.

152. Astellas denies the allegations in Paragraph 152.

153. Astellas admits that Plaintiffs and the purported class seek the damages described in Paragraph 153. Astellas denies that it violated any law, denies that Plaintiffs or any member of the putative class are entitled to any relief, denies that this action should be certified as a class action, and denies any remaining allegations of Paragraph 153.

COUNT II
(Unjust Enrichment and Imposition of Constructive Trust)

154. Astellas repeats, and incorporates by reference, the answers in ¶¶ 1 – 153 above.

155. Astellas admits that Plaintiffs purport to bring a count of unjust enrichment as described in Paragraph 155 as representatives of the putative class described in Paragraph 7.

156. Astellas denies the allegations in Paragraph 156.

157. Astellas denies the allegations in Paragraph 157.

158. The allegations in Paragraph 158 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the allegations of Paragraph 158.

159. The allegations in Paragraph 159 purport to state legal conclusions to which an answer is neither appropriate nor required; to the extent that an answer is required, Astellas denies the allegations of Paragraph 159.

PRAYER FOR RELIEF

Astellas denies that Plaintiffs are entitled to any relief, including, but not limited to the relief requested in the "Demand for Relief" clause of this Complaint. In particular, Astellas denies that this action may be maintained as a class action; denies that any member of the putative class is entitled to equitable relief; denies that any member of the putative class is entitled to damages; denies that any member of the putative class is entitled to the costs of suit or reasonable attorneys' fees; and denies that the putative class is entitled to any other relief.

JURY DEMAND

No response is required, as the "Jury Demand" clause of this Complaint does not contain any factual allegations.

ASTELLAS'S AFFIRMATIVE DEFENSES

In further answer to the Complaint, Astellas states that Plaintiffs' claims are barred in whole or in part by the following defenses. Astellas does not assume the burden of proof on any such defenses that would otherwise rest on Plaintiffs. Astellas has not knowingly or intentionally waived any applicable affirmative or other defenses. Astellas reserves the right to amend its Answer and/or to assert and rely upon such other defenses as may become available or apparent during discovery in this case.

First Affirmative Defense

Astellas's conduct is protected under the *Noerr-Pennington* doctrine and/or otherwise under the Constitution of the United States of America. Under the First Amendment to the Constitution of the United States of America and the *Noerr-Pennington* doctrine, Astellas's conduct is protected activity that cannot be the basis for liability under the antitrust laws.

Second Affirmative Defense

Plaintiffs fail to state a claim upon which relief can be granted.

Third Affirmative Defense

Plaintiffs and the putative class lack Article III and antitrust standing.

Fourth Affirmative Defense

Plaintiffs and the putative class have suffered no injury or damages as a result of the conduct alleged in this Complaint.

Fifth Affirmative Defense

Plaintiffs and the putative class have suffered no antitrust injury as a result of the conduct alleged in this Complaint.

Sixth Affirmative Defense

At all times, Astellas has acted in good faith and in furtherance of its legitimate business interests and has caused no injury to competition, the public, Plaintiffs, or the putative class.

Seventh Affirmative Defense

Plaintiffs and/or members of the putative class have failed to mitigate their damages.

Eighth Affirmative Defense

The claims of Plaintiffs and the putative class are barred because any injury they allegedly suffered is too remote and indirect, including (without limitation) under *Associated General Contractors v. California State Council of Carpenters*, 459 U.S. 519 (1983), and similar cases under the laws of the states at issue in this case.

Dated: April 26, 2012

Respectfully submitted,

By: /s/ Elizabeth K. Levine

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CERTIFICATE OF SERVICE

I, Elizabeth K. Levine, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants.

/s/ Elizabeth K. Levine

Elizabeth K. Levine
GOULSTON & STORRS

Counsel For Defendant Astellas Pharma US, Inc.

Dated: April 26, 2012